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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,622	01/09/2002	Olga Bandman	PF-0185-2 CON	1927
27904	7590	03/09/2004	EXAMINER	
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			SAOUD, CHRISTINE J	
			ART UNIT	PAPER NUMBER

1647

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/044,622	Applicant(s) BANDMAN ET AL.	
	Examiner Christine J. Saoud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,10,12-16 and 58-64 is/are pending in the application.
- 4a) Of the above claim(s) 1,14-16 and 58-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7,9,10,12 and 13 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>010902</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in Paper filed 10 November 2003 is acknowledged. The traversal is on the ground(s) that (1) Groups V, XII, and XIII should be rejoined upon allowance of product claims, (2) there is "minimal" burden to examine Group XVIII directed to microarrays, and (3) there is no burden to examine Group I because the search of the elected invention would substantially overlap with the search of Group I. This is not found persuasive because (1) there is no indication of allowable product claims at present, so rejoinder of Groups V, XII and XIII would be premature, at best. Additionally, Group V is not a method of using the product, but rather, a method of detecting the product, therefore, it would not be subject to rejoinder even upon an indication of an allowable product claim. (2)-(3) Undue burden can be established by a showing of different classification, different field of search, or by a showing of non-coextensive literature searches; this was established in the previous Office action and Applicant has not provided any evidence to the contrary.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 14-16 and 58-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed 10 November 2003.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is **required** to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the base claim. In the instant case, the nucleic acid of claim 3 could be infringed without infringing the claim from which it depends, i.e. the protein claim. Therefore, the claim is improperly dependent and should be rewritten in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 depends from a canceled claim (claim 2), therefore, it is not clear what limitations are intended by the claim. No meaningful interpretation can be made as to the subject matter of the claim and it will not be further treated on the merits.

Claims 5 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims include language such as "a polynucleotide sequence of SEQ ID NO:2". This language implies that there is more than one sequence associated with SEQ ID NO:2. There is no antecedent basis for multiple sequences of SEQ ID NO:2 and the claims are indefinite. This ground of rejection could be avoided by using the term "the" in place of "a" which would denote that SEQ ID NO:2 is a single sequence.

Applicant should note that the language in claim 1 (non-elected claim, but the basis for claim 3) also includes similar language of "an amino acid sequence of SEQ ID NO:1". This is also indefinite for the same reasons as applied to claims 5 and 12 because SEQ ID NO:1 is a single sequence but "an amino acid sequence of SEQ ID NO:1" implies multiple sequences. This is indefinite and upon correction of dependency for claim 3, this language should also be corrected.

Claims 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to complementary polynucleotides. However, the instant specification indicates at page 7 that:

Complementarity between two single-stranded molecules may be "partial", in which only some of the nucleic acids bind, or it may be complete when total complementarity exists between the single stranded molecules. The degree of complementarity between nucleic acid strands has significant effects on the efficiency and the strength of hybridization between nucleic acid strands.

Based on this definition, the metes and bounds of "complementary" cannot be determined since "partial" complementarity is included by the terminology and this only requires "some of the nucleic acids bind". Page 7, lines 29-30 indicate that partial degree of complementarity is lacking when the sequences have less than about 30% identity, further adding to the confusion as what degree of complementarity is intended by the claims and is in conflict with the statement that complementarity only requires some of the nucleic acids bind. Based on the broadest interpretation of the definition, the claims could encompass any nucleic acid in existence since optimized alignment would more likely than not provide "some" nucleic acids that bind. Therefore, the metes and bounds of the claims cannot be determined. An art rejection will not be made at this time since it is not clear what the claim encompasses. Any amendment or response which clearly defines complementary may require a new ground of rejection under 102. However, any new ground of rejection under 102 will be necessitated by Applicant's amendment or response and the next Office action could still be made final.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3, 5-7, 9-10 and 12-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility. The instant application does not disclose the biological role of the claimed invention or its significance.

The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of the claimed invention or its significance. The instant specification asserts that it provides compositions that may be used for diagnosis, prevention and treatment of cancer and other conditions or diseases involving angiogenesis and cell proliferation (see specification at page 1, lines 3-4 and page 10, line 30 to page 11, line 1). The specification asserts that the protein encoded by the claimed polynucleotides could be used to promote revascularization following traumatic amputation and surgical reconstruction or added to a tissue culture to promote vasculogenesis in tissues for autologous or heterologous transplant (page 23, lines 24-26 of the specification), antagonists or inhibitors could be administered to suppress or prevent angiogenesis and therefore the growth and development of cancers including, but not limited to cancers of the brain, breast, intestine, kidney, lung, ovary, pancreas, prostate, and uterus (page 24, lines 2-6).

These utilities are not considered to be specific and/or substantial because the specification fails to disclose any particular function or biological significance for the novel endothelial growth factor (NVR, as designated in the instant specification) of the instant invention and the asserted uses are not "real world" at the time the instant

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application was filed. The disclosed protein, whose cDNA has been isolated, is alleged to have a potential function based upon its amino acid sequence similarity to another known protein. After further research, a specific and substantial credible utility might be found for the claimed isolated compositions. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are useful to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of useful as it appears in 35 U.S.C. 101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility.

The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a polynucleotide encoding a protein of as yet undetermined function or biological significance. There is no evidence of record or any

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line of reasoning that would support a conclusion that the polynucleotide encoding the NVR protein of the instant application was or is, as of the filing date, useful for diagnosis, prevention and treatment of cancer and other conditions or diseases involving angiogenesis and cell proliferation as stated at pages 1 and 10-11 of the specification. Until some actual and specific significance can be attributed to the protein identified in the specification as NVR, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date. In the absence of knowledge of the receptor to which NVR binds, or the biological significance of this protein, or evidence of a correlation between expression of the claimed invention and a disease or disorder, there is no immediately evident patentable use for it. To employ the claimed invention in any of the disclosed methods would clearly be using it as the object of further research. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the claimed nucleic acids or encoded protein, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C.101 as being useful.

The specification alleges use of the claimed invention for the treatment of diseases (either by administering the encoded polypeptide, administration of antibodies to the encoded polypeptide, administration of nucleic acids of the claimed invention, etc.). However, this asserted utility is not substantial because the claimed invention has not been shown to be involved with any disease or disorder, therefore, it would require a

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substantial inventive contribution to determine which disease or disorder may or may not be involved with the claimed invention, and therefore, could be treated using the claimed invention. The specification alleges the use of the claimed invention for diagnosis of diseases and disorders. This asserted utility is not substantial because there is no evidence that the claimed invention is associated or correlated with any disease or disorder and such a disclosure does not provide a specific benefit in currently available form. The diseases and/or conditions that are recited in the specification do not have a common mode of action or are related in such a way that one of ordinary skill in the art would reasonably expect the presence of NVR to be predictive of those diseases and/or conditions. Furthermore, the instant specification fails to indicate whether NVR is upregulated, downregulated, present or absent when these conditions/diseases are present, so an artisan would not be able to measure the claimed invention and make an informed observation regarding disease state. The instant specification fails to demonstrate differential expression in that there is no evidence to show that NVR is not expressed in normal tissues and that it is only found in the listed diseased tissues, which is further evidence of a lack of substantial utility.

The artisan would first need to determine which diseases, disorders or conditions are associated with the claimed invention before being able to use the claimed invention for the asserted use of diagnosis or as a diagnostic; this does not define a patentable utility or a specific benefit in currently available form. Additionally, the specification alleges that the claimed invention could be used in drug screening methods. However, this asserted utility does not rise to the level of a patentable utility because it is not

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substantial at the time the instant invention was filed. Without knowing the biological significance of the claimed invention, the artisan would not know how to interpret the results of a drug screen. For example, the specification indicates use of the encoded protein for screening of compounds having suitable binding affinity. What use is a compound which binds the encoded protein of the claimed invention if the artisan does not know the significance of the invention? If the claimed invention is inhibited by a drug, or stimulated by a drug, what is the significance of this result? No meaningful interpretation of the results of the drug screen can be made because the invention does not provide a specific benefit in currently available form (i.e. no substantial utility).

Claims 3, 5-7 9-10 and 12-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0819. The examiner can normally be reached on mtr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud